

***Claim Objections***

The objection of claims 2, 5 and 20 have been overcome through this Amendment.

***Claims Rejections under 35 U.S.C §102***

Claims 1-2, 5-6, 24-25, 27 and 29-30 were rejected under 35 U.S.C. §102(b) as anticipated by Molock (US 5,292,350). For the following reasons, the Examiner's rejection is respectfully traversed.

Molock discloses a soft, hydrogel contact lens which has a dye dispersing uniformly throughout the lens. However, Molock does not disclose nor suggest anything about an ophthalmic moulding (e.g. a contact lens) having particles of a pigment incorporated therein and about an ophthalmic moulding (e.g. a contact lens) comprising a polymer matrix comprising a polysiloxane and having high oxygen permeability. Applicants respectfully submit that the present invention as currently claimed are not anticipated or rendered obvious by Molock, since the cited reference does not contain all of the elements of the claimed invention. Applicants respectfully request withdrawal of the 35 U.S.C. §102(b) rejection.

Claims 1-3, 5-8, 24-25, 27 and 29-30 were rejected under 35 U.S.C. §102(b) as anticipated by Foley (US 4,252,421). Applicants respectfully submit that, since Foley does not disclose nor suggest anything about an ophthalmic moulding (e.g. a contact lens) comprising a polymer matrix comprising a polysiloxane and having high oxygen permeability, the present invention as currently claimed are not anticipated or rendered obvious by Foley. Applicants respectfully request withdrawal of the 35 U.S.C. §102(b) rejection.

***Claims Rejections under 35 U.S.C §103***

Claims 3-4 were rejected under 35 U.S.C. §103(a) as being unpatentable over Grolier in view of Molock (US 5,292,350). For the following reasons, the Examiner's rejection is respectfully traversed.

Applicants submit that both the primary reference (Grolier) and the secondary reference (Molock) do not disclose nor suggest anything about an ophthalmic moulding (e.g. a contact lens) having particles of a pigment incorporated therein and about an ophthalmic moulding (e.g. a contact lens) comprising a polymer matrix comprising a polysiloxane and having high oxygen permeability. Therefore, Applicants respectfully submit that, a *prima facie* case of obviousness can not be established and request withdrawal of the 35 U.S.C. §103(a) rejection.

Claim 23 was rejected under 35 U.S.C. §103(a) as being obvious over Molock. As discussed above, Molock does not disclose nor suggest anything about an ophthalmic moulding (e.g. a contact lens) having particles of a pigment incorporated therein and about an ophthalmic moulding (e.g. a contact lens) comprising a polymer matrix comprising a polysiloxane and having high oxygen permeability. Therefore, Applicants respectfully submit that, a *prima facie* case of obviousness can not be established and request withdrawal of the 35 U.S.C. §103(a) rejection.

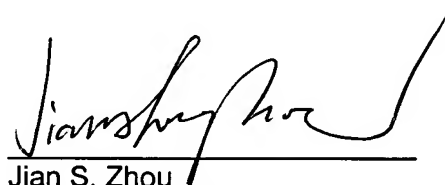
Claim 23 was rejected under 35 U.S.C. §103(a) as being obvious over Foley. As discussed above, Foley does not disclose nor suggest anything about an ophthalmic moulding comprising a polymer matrix comprising a polysiloxane and having high oxygen permeability. Therefore, Applicants respectfully submit that, a *prima facie* case of obviousness can not be established and request withdrawal of the 35 U.S.C. §103(a) rejection.

### **CONCLUSION**

In view of the foregoing and in conclusion, Applicants submit that the 35 U.S.C. §102 and §103 rejections set-forth in the Office Action have been overcome, and that the pending claims are not anticipated or obvious over the cited art, either individually or in combination. Applicants request reconsideration and withdrawal of the rejections set-forth in the Office Action.

Should the Examiner believe that a discussion with Applicants' representative would further the prosecution of this application, the Examiner is respectfully invited to contact the undersigned. Please address all correspondence to Thomas Hoxie, Novartis Corporation, Corporate Intellectual Property, One Health Plaza, Bldg. 430, East Hanover, NJ 07936-1080. The Commissioner is hereby authorized to charge any other fees which may be required under 37 C.F.R. §§1.16 and 1.17, or credit any overpayment, to Deposit Account No. 19-0134.

Respectfully submitted,

  
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**Version with Markings to Show Changes Made****In the specification:**

Please amend the second paragraph on page 17 as follows:

The amount of pigment necessary in a particular application may vary within wide limits dependent, in part, upon the desired final product dimensions and desired visible and/or ultraviolet light transmission. For example, an amount of pigment is chosen so that the optical transmission of the final molding or lens is, for example, greater than 80%, preferably greater than 90%, more preferably from about 92% to about 99.5%, and most preferably from about 93% to about 97%. The above transmission values refer to a 100-[Φ]μm center thickness of the lens and to the wavelength of the absorption maximum of the respective pigment. The amount of pigment necessary to achieve the optical transmission is advantageously chosen so that the weight percentage of pigment, based on the total weight of the polymer precursor, and optional comonomers present in the prepolymerization mixture according to step (c), is from about 0.0001% to about 0.05%. Preferably, the weight percentage of pigment is from about 0.0001% to about 0.02%. More preferably, the weight percentage of pigment is from about 0.0001% to about 0.01%.

Please amend the third paragraph on page 17 as follows:

The particle size of the pigment may vary within wide limits. In general, the particle size should be small enough to avoid light scattering, which is clinically significant for the degree of tint intensity required. An average or median particle size (as measured by HORIBA LA-910 particle size analyzer) of less than or equal to about 4 [Φ]μm, preferably less than or equal to about 0.6 [Φ]μm, more preferably from about 0.05 Φm to about 1 [Φ]μm, and even more preferably from about 0.05 [Φ]μm to about 0.5 [Φ]μm has proven advantageous.

Please amend the paragraph bridging pages 27 and 28 as follows:

A polysiloxane macromer is prepared by reacting, at room temperature (about 21°[ E]C), one mole equivalent (about 100 grams) of poly(dimethylsiloxane) dialkanol (Shin Etsu Chemical Co., Tokyo, Japan) having hydroxyethyl propoxy end groups with 2 mole equivalents (about 21.2 grams) of isophorone diisocyanate (Aldrich Chemical Co., Milwaukee, Wis.) in the presence of about 0.2 grams dibutyltin dilaurate catalyst (Pfaltz & Bauer, Inc., Waterbury, Connecticut). After

about 48 hours reaction time, 2.02 mole equivalents (about 38.7 grams) of poly(ethylene glycol) ("PEG", about 610 g/mol Mn, Dow Chemical Corp., Midland, Mich.) and about 0.17 grams of dibutyltin dilaurate (about 0.43% by weight PEG) are added to 80 grams of the reaction product from the prior step. Sufficient chloroform (Aldrich Chemical Co. ) is added to the mixture to make the mixture homogeneous. This mixture is stirred at room temperature for about 15 hours. Next, the mixture is stirred for about 8 hours at a temperature of about 44 to 48°C, with the temperature held substantially constant by a surrounding oil bath. The chloroform is then evaporated, in order to achieve a final concentration of about 50% by weight solids, by stirring the mixture at room temperature for about 8 hours. Then, about 2.14 mole equivalents (about 10.4 grams) of isocyanatoethyl methacrylate ("IEM", Monomer Polymer, Inc., Feasterville, Pa) is added to the mixture. Finally, the mixture is covered with aluminum foil and stirred at room temperature for about 17 hours, yielding a polysiloxane-containing macromer having a number-average molecular weight (Mn) of about 4000 grams per mole.

Please amend the paragraph bridging pages 28 and 29 as follows:

51.5g (50 mmol) of the perfluoropolyether Fomblin® ZDOL (from Ausimont S.p.A, Milan) having a mean molecular weight of 1030 g/mol and containing 1.96 meq/g of hydroxyl groups according to end-group titration is introduced into a three-neck flask together with 50mg of dibutyltin dilaurate. The flask contents are evacuated to about 20 mbar with stirring and subsequently decompressed with argon. This operation is repeated twice. 22.2 g (0.1mol) of freshly distilled isophorone diisocyanate kept under argon are subsequently added in a counterstream of argon. The temperature in the flask is kept below 30°C. by cooling with a water bath. After stirring overnight at room temperature, the reaction is complete. Isocyanate titration gives an NCO content of 1.40 meq/g (theory: 1.35 meq/g). 202. of the  $[\gamma, \tau]_{\alpha, \omega}$ -hydroxypropyl-terminated polydimethylsiloxane KF-6001 from Shin-Etsu having a mean molecular weight of 2000g/mol (1.00meq/g of hydroxyl groups according to titration) are introduced into a flask. The flask contents are evacuated to approx. 0.1 mbar and decompressed with argon. This operation is repeated twice. The degassed siloxane is dissolved in 202 ml of freshly distilled toluene kept under argon, and 100 mg of dibutyltin dilaurate (DBTDL) are added. After complete homogenization of the solution, all the perfluoropolyether reacted with isophorone diisocyanate (IPDI) is added under argon. After stirring overnight at room temperature, the reaction is complete. The solvent is stripped off under a high vacuum at room temperature. Microtitration shows 0.36meq/g of hydroxyl groups (theory 0.37meq/g). 13.78 g (88.9 mmol) of 2-isocyanatoethyl methacrylate (IEM) are added under argon to 247 g of the  $[\gamma, \tau]_{\alpha, \omega}$ -

hydroxypropyl-terminated polysiloxane-perfluoropolyether-polysiloxane three-block copolymer (a three-block copolymer on stoichiometric average, but other block lengths are also present). The mixture is stirred at room temperature for three days. Microtitration then no longer shows any isocyanate groups (detection limit 0.01 meq/g). 0.34 meq/g of methacryl groups are found (theory 0.34 meq/g).

Please amend the third paragraph on page 29 as follows:

Reaction of [ $\square, \square$ ] $\alpha, \omega$ -bis-aminopropyl-dimethylpolysiloxane with D(+)-gluconic acid d-lactone:

Before the reaction, the amino-functionalized polydimethylsiloxane employed for the synthesis (X-22-161-C, Shin Etsu, JP) was finely dispersed in acetonitrile, extracted and then subjected to molecular distillation.

Please amend the paragraph bridging pages 29 and 30 as follows:

The following reactions take place with exclusion of  $H_2$ . 0.200 g of purified amino-functionalized polydimethylsiloxane (0.375 meq of  $NH_2$  /g;  $M_n$ (VPO) 3400-3900 (VPO, Vapour Pressure Osmometry)), dissolved in 200 ml of absolute THF, are slowly added dropwise to a suspension of 13.35 g (75 mmol) of D(+)-gluconic acid d-lactone in 50 ml of absolute THF and the mixture is stirred at 40°C. for about 24 hours until the lactone has reacted completely. (Monitoring of the reaction by thin layer chromatography (TLC): silica gel; i-propanol/ $H_2O$  ethyl acetate 6:3:1; staining with Ce(IV) sulfate/phosphoromolybdic acid solution (CPS reagent)). After the reaction, the reaction solution is concentrated to dryness and the residue is dried under 3 Pa (0.03 mbar) for 48 hours. 213.3 g of [ $\nabla, T$ ] $\alpha, \omega$ -bis(3-gluconamidopropyl)-poly-dimethylsiloxane are obtained. Titration of the amino groups with perchloric acid shows a conversion of the amino groups of more than 99.8%.

Please amend the second paragraph on page 30 as follows:

In a dry box under nitrogen atmosphere, about 200 grams of dry PDMS dipropoxyethanol (Shin-Etsu) is added to a container. Isocyanatoethyl methacrylate (IEM) in an amount equal to about 2 moles per mole PDMS dialkanol is added to the container. About 0.1 weight percent dibutyltin dilaurate (DBTL) catalyst, based on PDMS dialkanol weight, is added to the container along with a stir bar. The container is immersed in an oil bath atop a stir plate, and secured in place with a clamp. A stream of UPC air at about 2 psig is passed over the mixture. The mixture is agitated at room temperature (about 22°C.) for about 24 hours. An iterative procedure follows

in which the mixture is analyzed for isocyanate content and IEM is added if the PDMS dialkoxymethanol has not been completely reacted. The mixture is stirred about 24 hours more. The macromer produced is a siloxane-containing macromer.

Please amend the second paragraph on page 31, lines 7-14 as follows:

A mean particle size of approximately  $-0.35[\Phi]\mu\text{m}$ , with >80% of the particles smaller than  $0.45[\Phi]\mu\text{m}$ , and all the particles  $<2[\Phi]\mu\text{m}$  in size is achieved. The yield of dispersion is approximately 80%. Particle size is analyzed on a HORIBA LA-910 or 920, using ethanol as the solvent, with sonication for 3 minutes prior to measurement. Preferably, particle-size is measured before and after sonication.

**In the claims:**

Please amend claims 1, 2, 5, 9, 20, 21, 24, 26, 28 and 29 as follows:

1. (Amended) A soft, tinted ophthalmic molding comprising:
  - (i) a polymer matrix comprising a polysiloxane and having high oxygen permeability; and incorporated therein
  - (ii) particles of a pigment.
2. (Amended) The soft, tinted ophthalmic molding of claim 1, wherein the polymer matrix is a core material and is at least in part surrounded by an ophthalmically compatible surface.
5. (Amended) The soft, tinted ophthalmic molding of claim 1, wherein the polymer matrix [comprises] is a polymerization product of at least one [a] polysiloxane-containing macromer and at least one vinylic comonomer.[, fluorosiloxane, fluorine-containing monomer, hydrophilic monomer, hydrophobic monomer, or a copolymer thereof, or a mixture thereof.]
9. (Amended) A method for making a soft, tinted ophthalmic molding comprising:
  - (a) providing a polymer precursor capable of forming a polymer or copolymer having high oxygen permeability;
  - (b) providing a pigment dispersion comprising particles of a pigment and a dispersing agent;
  - (c) mixing the pigment dispersion and the polymer precursor to form a tinted prepolymer mixture;

- (d) dispensing the tinted prepolymer mixture into a mold; and
  - (e) cross-linking or polymerizing the tinted prepolymer mixture in the mold to form a soft, tinted ophthalmic molding having high oxygen permeability comprising a polymer matrix and the pigment entrapped therein.
20. (Amended) The method of claim 9, wherein the dispersing agent is selected from the group consisting of methyl methacrylate, isobutyl acrylate, isooctyl acrylate, isodecyl acrylate, 2-ethylhexyl acrylate, hexafluorobutyl (meth)acrylate, HEMA, TRIS, [and] acrylonitrile, [or a] and mixtures thereof.
21. (Amended) The method of claim 9, wherein the weight percentage of the particles of the pigment, based on the total weight of the prepolymer mixture, is from greater than zero to about 0.05 weight percent.
24. (Amended) A soft, tinted ophthalmic lens comprising the reaction product of:
- (i) a cross-linkable or polymerizable material including a siloxane-containing macromer, wherein the cross-linkable or polymerizable material is capable of forming a polymer or copolymer having high oxygen permeability; and
  - (ii) a pigment dispersion comprising particles of a pigment and a dispersing agent.
26. (Amended) The soft, tinted ophthalmic lens of claim 24, wherein the [cross-linkable or polymerizable material comprises a] siloxane-containing macromer has[ving] a dialkyl siloxane group.
28. (Amended) The soft, tinted ophthalmic lens of claim [24]26, wherein [the cross-linkable or polymerizable material comprises a siloxane-containing macromer having a dialkyl siloxane group and] the dispersing agent is TRIS.
29. (Amended) A composition for making a soft, tinted ophthalmic lens comprising:
- (i) a cross-linkable or polymerizable material including a siloxane-containing macromer, wherein the cross-linkable or polymerizable material is capable of forming a polymer or copolymer having high oxygen permeability; and
  - (ii) a pigment dispersion comprising particles of a pigment and a dispersing agent.